IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al., *Plaintiffs*, v. DALE FOLWELL, et al., *Defendants*.	No. 1:19-cv-00272-LCB-LPA

THIRD SUPPLEMENTAL DECLARATION OF AMY RICHARDSON

I, Amy Richardson, do hereby declare as follows:

1. I am more than 18 years of age, have personal knowledge of the facts set forth herein, and am otherwise competent to testify to the matters set forth herein.

2. I am a partner with Harris, Wiltshire & Grannis LLP, and counsel for Plaintiffs in this matter. I submit this declaration in support of Plaintiffs' Reply in Support of Plaintiffs' Motion for Summary Judgment.

3. Attached to this declaration are true and correct copies of the documents listed in the table below. Entries in the table indicate where documents have been excerpted or have had highlighting applied to indicate the relevant portions of the document.

Exhibit	Description
R1	CVS/Caremark "Specialty Guideline Management – North Carolina State Health Plan: Lupron Depot 3.75mg (leuprolide acetate for depot suspension) Lupron Depot-3 Month 11.25mg (leuprolide acetate for depot suspension)," dated 2016, KADEL00130527
R2	CVS/Caremark "Specialty Guideline Management – North Carolina State Health Plan: Lupron Depot 3.75mg (leuprolide acetate for depot suspension) Lupron Depot-3 Month 11.25mg (leuprolide acetate for depot suspension)," dated 2017, KADEL00265955
R3	CVS/Caremark "Specialty Guideline Management – Triptodur (triptorelin)," KADEL00290571
R4	CVS/Caremark "Specialty Guideline Management – Supprelin LA (histrelin acetate)," KADEL00294761
R5	CVS/Caremark "Specialty Guideline Management – Eligard (leuprolide acetate)," KADEL00309332
R6	CVS/Caremark "Specialty Guideline Management – Trelstar (triptolerin pamoate)," KADEL00308907
R7	CVS/Caremark "Specialty Guideline Management – Vantas (histrelin acetate)," KADEL00297881
R8	Excerpt of Dep. Tr. of Dan H. Karasic, M.D.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: February 2, 2022

/s/ Amy Richardson
Amy Richardson

CERTIFICATE OF SERVICE

I certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system which will send notification of such filing to all registered users.

Dated: February 2, 2022

/s/ Amy E. Richardson

Amy E. Richardson
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Exhibit R1

CVS/caremark

SPECIALTY GUIDELINE MANAGEMENT

North Carolina State Health Plan:
Lupron Depot 3.75mg (leuprolide acetate for depot suspension)
Lupron Depot-3 Month 11.25mg (leuprolide acetate for depot suspension)

PROGRAM RATIONALE
Client Requested: The intent of the criteria is to ensure that patients follow selection elements established by North Carolina State Health Plan's Commercial Prior Authorization Approval policy.

PRIOR AUTHORIZATION CRITERIA[1]
Coverage is provided for:
- Endometriosis
- Uterine Leiomyomata (fibroids)
- Gender Dysphoria

FDA-APPROVED INDICATIONS[2,3]
1. Endometriosis
   - Lupron Depot 3.75mg and Lupron Depot-3 Month 11.25mg is indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot with norethindrone acetate 5 mg daily is also indicated for initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment and retreatment should be limited to six months.
2. Uterine Leiomyomata (Fibroids)
   - Lupron Depot 3.75mg and Lupron Depot-3 Month11.25mg, concomitantly with iron therapy, is indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. Lupron may be added if the response to iron alone is considered inadequate. Recommended duration of therapy with Lupron Depot 3.75 mg and 11.25 mg is up to 3 months. (The 11.25 mg dosage form is indicated only for women for whom three months of hormonal suppression is deemed necessary.)

CRITERIA FOR APPROVAL

1. What is the diagnosis?
   a. Endometriosis → *Approve 6 months*
   b. Uterine Leiomyomata (fibroids) → *Approve 3 months*
   c. Gender Dysphoria→ *Approve 12 months*
   d. Other → *Deny*

REFERENCES

1. North Carolina State Health Plan Commercial Prior Authorization Approval Policy.
2. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2013.
3. Lupron Depot-3 Month 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2013.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (ST) 06/2016
Revised:	ST 12/2016 (added gender dysphoria)
Reviewed:	CDPR/LCB 06/2016, ME 02/2017

The Participating Group signed below hereby accepts and adopts as its own the criteria for use with Specialty Guideline Management, as administered by CVS/caremark.

_____ _____
Signature Date

_____
Client Name

Exhibit R2

Reference number(s)
C11969-A

SPECIALTY GUIDELINE MANAGEMENT

North Carolina State Health Plan:
Lupron Depot 3.75mg (leuprolide acetate for depot suspension)
Lupron Depot-3 Month 11.25mg (leuprolide acetate for depot suspension)

PROGRAM RATIONALE
Client Requested: The intent of the criteria is to ensure that patients follow selection elements established by North Carolina State Health Plan's Commercial Prior Authorization Approval policy.

PRIOR AUTHORIZATION CRITERIA[1]
Coverage is provided for:
- Endometriosis
- Uterine Leiomyomata (fibroids)

FDA-APPROVED INDICATIONS[2,3]
1. Endometriosis
   - Lupron Depot 3.75mg and Lupron Depot-3 Month 11.25mg is indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot with norethindrone acetate 5 mg daily is also indicated for initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment and retreatment should be limited to six months.
2. Uterine Leiomyomata (Fibroids)
   - Lupron Depot 3.75mg and Lupron Depot-3 Month11.25mg, concomitantly with iron therapy, is indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. Lupron may be added if the response to iron alone is considered inadequate. Recommended duration of therapy with Lupron Depot 3.75 mg and 11.25 mg is up to 3 months. (The 11.25 mg dosage form is indicated only for women for whom three months of hormonal suppression is deemed necessary.)

CRITERIA FOR APPROVAL

1. What is the diagnosis?
   a. Endometriosis → *Approve 6 months*
   b. Uterine Leiomyomata (fibroids) → *Approve 3 months*
   c. Gender Dysphoria→ *Deny*
   d. Other → *Deny*

REFERENCES

1. North Carolina State Health Plan Commercial Prior Authorization Approval Policy.
2. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; May 2017.
3. Lupron Depot-3 Month 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; May 2017.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (ST) 06/2016
Revised:	ST 12/2016 (added gender dysphoria), TE 12/2017 (removed gender dysphoria)
Reviewed:	CDPR/LCB 06/2016, ME 02/2017, ME 12/2017

The Participating Group signed below hereby accepts and adopts as its own the criteria for use with Specialty Guideline Management, as administered by CVS/Caremark.

_____ _____
Signature Date

_____
Client Name

Exhibit R3

Reference number(s)
2190-A, 2504-A

SPECIALTY GUIDELINE MANAGEMENT

TRIPTODUR (triptorelin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Triptodur is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty.

B. Compendial Use
Gender dysphoria (also known as gender non-conforming or transgender persons)
NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when ALL of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay.
   b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age.
   c. The member was less than 8 years of age at the onset of secondary sexual characteristics.

2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when ALL of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay.
   b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age.
   c. The member was less than 9 years of age at the onset of secondary sexual characteristics.

B. Gender dysphoria

1. Authorization of 12 months may be granted for pubertal suppression in preparation for gender reassignment in an adolescent member when ALL of the following criteria are met:
   a. The member has a diagnosis of gender dysphoria
   b. The member has reached Tanner stage 2 of puberty

2. Authorization of 12 months may be granted for gender reassignment in an adult member when ALL of the following criteria are met:
   a. The member has a diagnosis of gender dysphoria
   b. The member will receive Triptodur concomitantly with cross sex hormones

III. CONTINUATION OF THERAPY

A. CPP

1. Authorization up to age 12 may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age.
2. Authorization up to age 13 may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age.

B. Gender Dysphoria

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Triptodur [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; September 2017.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.
3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics.* 2009;123:e752-e762.
4. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics.* 2009;123:e1059-e1063.
5. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics.* 2016;137:e20153732.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017:102(11):3869–3903.
7. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
8. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R4

Reference number(s)
1973-A, 2078-A

SPECIALTY GUIDELINE MANAGEMENT

Supprelin LA (histrelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Supprelin LA is indicated for the treatment of children with central precocious puberty.

B. Compendial Use
Gender Dysphoria (also known as gender non-conforming or transgender persons)
NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when ALL of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay
   b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
   c. The member was less than 8 years of age at the onset of secondary sexual characteristics

2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when ALL of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay
   b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
   c. The member was less than 9 years of age at the onset of secondary sexual characteristics

III. CONTINUATION OF THERAPY

A. CPP

1. Authorization up to age 12 may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age.
2. Authorization up to age 13 may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age.

IV. REFERENCES

1. Supprelin LA [package insert]. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; May 2017.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.
3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics.* 2009;123:e752-e762.
4. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics.* 2009;123:e1059-e1063.
5. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics.* 2016;137:e20153732.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017:102(11):3869–3903.
7. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
8. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R5

Reference number(s)
1966-A, 2084-A

SPECIALTY GUIDELINE MANAGEMENT

ELIGARD (leuprolide acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer
   a. Adjuvant therapy for lymph node-positive disease found during pelvic lymph node dissection (PLND)
   b. Initial androgen deprivation therapy (ADT) for:
      i. Intermediate risk group
      ii. High or very high risk group
      iii. Regional disease
      iv. Metastatic disease
   c. Recurrent disease in patients who experience biochemical failure after previous therapy
   d. Progressive castration-naïve disease
2. Gender Dysphoria (also known as gender non-conforming or transgender persons)
   NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage for prostate cancer will not be provided when Eligard is used as neoadjuvant therapy prior to radical prostatectomy.

III. CRITERIA FOR INITIAL APPROVAL

A. Prostate Cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Eligard [package insert]. For Collins, CO: Tolmar Pharmaceuticals; January 2017.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 09, 2016.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 3.2016. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed November 10, 2016.
4. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2009;94:3152-3154.
5. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
6. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R6

Reference number(s)
1968-A, 2085-A

SPECIALTY GUIDELINE MANAGEMENT

TRELSTAR (triptorelin pamoate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
   1. Palliative treatment of advanced prostate cancer

B. Compendial Uses
   1. Prostate cancer
      a. Adjuvant therapy for lymph node-positive disease found during pelvic lymph node dissection (PLND)
      b. Initial androgen deprivation therapy (ADT) for:
         i. Intermediate risk group
         ii. High or very high risk group
         iii. Regional disease
         iv. Metastatic disease
      c. Recurrent disease in patients who experience biochemical failure after previous therapy
      d. Progressive castration-naïve disease
   2. Gender dysphoria (also known as gender non-conforming or transgender persons)
      NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage for prostate cancer will not be provided when Trelstar is used as neoadjuvant therapy prior to radical prostatectomy.

III. CRITERIA FOR INITIAL APPROVAL

A. Prostate Cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Trelstar [package insert]. Parsippany, NJ: Watson Pharma; August 2016.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 14, 2016.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 3.2016. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed November 09, 2016.
4. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009;94:3152-3154.
5. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
6. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R7

Reference number(s)
1969-A, 2086-A

SPECIALTY GUIDELINE MANAGEMENT

VANTAS (histrelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication[1]
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer[2]
2. Gender dysphoria (also known as gender non-conforming or transgender persons)[4-6]
NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer[1-3]
Authorization of 12 months may be granted for treatment of prostate cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Vantas [package insert]. Malvern, PA: Endo Pharmaceuticals; June 2017.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 29, 2017.

3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 2.2017. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed November 29, 2017.
4. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017:102(11):3869–3903.
5. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
6. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.

Exhibit R8

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No. 1:19-cv-00272

MAXWELL KADEL, et al.,
Plaintiffs,
vs.
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,
Defendants,

DEPOSITION OF DAN H. KARASIC, M.D.
Remote
September 20, 2021
9:00 a.m. Pacific Time

Prepared by:
Vicki L. O'Ceallaigh Champion, CR
Certificate No. 50534

Prepared for:

(Certified copy)

when we are referring to people with gender dysphoria, little-G-little-D, we are also maybe referring people -- to people who might meet a criteria -- might meet the criteria for the DSM diagnosis, but the DSM diagnosis is, you know -- has a specific set of criteria.

And the gender dysphoria, small letters, existed before those seven criteria were laid out, because that -- those criteria did not, you know, exist until 2013.

BY MR. KNEPPER:

Q. Do all transgender people suffer from the diagnosis of gender dysphoria?

MR. HASKEL: Objection to form, foundation.

A. So in the DSM, they put in a post-transition specifier, and specifically -- so the people -- people can get ongoing care post-transition, so -- so I think that that was put in specifically so that if people are being, you know, treated under that diagnosis and their -- their symptoms have alleviated because of treatment, they can continue getting treatment under that diagnosis.

BY MR. KNEPPER:

Q. Are there individuals -- does that mean that all individuals -- are there any other individuals

who are transgender who do not suffer from gender dysphoria other than individuals who are post-transition?

MR. HASKEL: Objection to form, foundation.

A. Are you asking me to make a diagnosis of all transgender people?

BY MR. KNEPPER:

Q. I'm asking you if the set of people who are transgender and the people -- and the set of people who suffer from gender dysphoria, the psychiatric diagnosis, are the same -- are the same. In other words, it's a one-to-one correlation.

Do all people who are transgender suffer from gender dysphoria, the psychiatric diagnosis?

MR. HASKEL: Object to the form, foundation.

A. So the DSM-5 and the APA make a distinction between people who have transgender identity and people who meet the criteria of the diagnosis for gender dysphoria making it, you know -- establishing that you have the diagnosis of gender dysphoria if you meet the criteria for it, but that transgender identity itself is not a mental illness.

BY MR. KNEPPER:

Q. I want to try to see if I can get a specific answer. Is your testimony that not all individuals who express a transgender identity have a diagnosed illness of gender dysphoria?

MR. HASKEL: Same objections, form, foundation.

A. I think I would just leave my testimony as it is.

BY MR. KNEPPER:

Q. I will try to get you to a "yes" or "no" then.

Do all transgender individuals suffer from gender dysphoria within the DSM-5 criteria?

MR. HASKEL: Objection; form, foundation, asked and answered.

A. So, again, I would -- I would say people meet the DSM diagnosis. They meet the criteria for it. If they meet the criteria for it, I can't say whether every person does. I do think one can say that the APA left an open door with the post-transition specifier to continue giving the diagnosis, you know, with that specifier for people even after they have received transition care.

BY MR. KNEPPER:

Q. So is your testimony that you do not know whether all individuals expressing a transgender identity suffer from gender dysphoria?

MR. HASKEL: Objection; form. Objection; foundation, mischaracterizing the witness's testimony.

A. Yeah. I said my testimony, and that's -- that's what it is.

BY MR. KNEPPER:

Q. Sure. Can you answer the following question "yes" -- I'm going to ask you whether you can answer the following question with a "yes" or "no" answer.

Do all individuals -- do all transgender individuals suffer from gender dysphoria as described in the DSM-5?

MR. HASKEL: Objection; form, foundation.

A. So, again, my testimony is what it is. I can't speak for every transgender people, for every transgender person. I think the APA left an open door for that diagnosis. I know, for example, in discussions --

BY MR. KNEPPER:

Q. Doctor -- Doctor -- I'm sorry to --

MR. HASKEL: If you could let the Witness

finish, and then you can ask --

MR. KNEPPER: I asked him a very specific question, Warren. I asked him whether he could answer that question "yes" or "no." And I haven't gotten --

MR. HASKEL: Hold on. Hold on. Let's let the record -- he was answering your question. I think there was testimony. The record is clear. If you want to strike that question and then ask your question again. I objected to form, foundation. I'm still --

MR. KNEPPER: This is going to be a very long day if I can't even get him to answer whether he can answer a "yes" or "no" question. It's very simple. If he can answer it, he can say "yes." If he can't answer it, he can say "no." At that point, if he --

MR. HASKEL: If he --

MR. KNEPPER: -- if he wants to say "no because," that's fine, but that's what I'm asking for.

BY MR. KNEPPER:

Q. Can you answer that question "yes" or "no," Dr. Karasic?

A. Well, I thought I was in the middle of

answering the question.

Q. Okay.

MR. HASKEL: Do you want to ask it again, Counsel, so we have a clear record.

MR. KNEPPER: Vicki -- Vicki, could you read that question back, please.

THE COURT REPORTER: Certainly. Give me just a moment.

(Requested portion of record read.)

MR. HASKEL: Objection; form, foundation.

A. Okay. So I don't need -- I was going to give you an example, but I would say "no."

BY MR. KNEPPER:

Q. Now, I would love to have the example. I wanted to make sure I had that answer on the record.

A. Okay. So when -- I know when we were in discussions about this when -- about the diagnosis of -- so discussions about the diagnosis of gender dysphoria, which is in DSM-5, and gender incongruence, which is in ICD-11 -- an example was given by Peggy Cohen-Kettenis, who was leading the efforts, along with Ken Zucker, for the gender dysphoria diagnosis in DSM-5 and was an essential person in the ICD-11 diagnosis.

And there was discussion about the

differences between gender dysphoria and gender incongruence, and an example given by Peggy Cohen-Kettenis was that there are sometimes -- sometimes children who were started at -- on puberty blockers who were not expressing gender dysphoria that was causing social or occupational dysfunction, because they seemed to be functioning similarly to gender peers, and so that was an example that Peggy Cohen-Kettenis gave.

And so the -- I think they intentionally, with DSM-5, had this post-transition specifier with ICD-11, they did not include a specifier for clinically significant distress or impairment and social and occupational functioning. And I think the intent in ICD-11 was to include all transgender people. Of note, though, ICD-11, the diagnosis was outside of the mental disorder chapter.

Q. Your testimony was that you can't answer "yes" or "no" to the question whether all transgender individuals suffer from gender dysphoria as defined by the DSM-5.

Are there -- are you aware of any --

A. I think there is an objection over there, but --

MR. HASKEL: Well, I don't think there was

actually a question. I think you were characterizing his testimony, which I don't know if that's a question or you were going to ask a question after --

MR. KNEPPER: Hold on. Hold on. I stopped, because I wanted to let Dr. Karasic speak.

MR. HASKEL: Okay.

MR. KNEPPER: I absolutely will finish my question, but I want to give the Witness -- when he raised his finger and said he wanted to say something, I wanted to give him an opportunity to make sure that I was saying something correctly.

BY MR. KNEPPER:

Q. So go ahead, Dr. Karasic.

A. So on that last answer, I was saying in the example I was giving was a "no" to the question of do all transgender people also have a diagnosis of gender dysphoria, and I was giving an example that related to the difference between gender dysphoria and gender incongruence of ICD-11, so just to clarify my answer --

Q. Thank you. That does -- that does clarify for me.

I'm going to ask you the converse question now. Do all individuals -- are all individuals who